

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re the application of: David Keith JAMES et al.

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Examiner: LAVERT, Nicole

Title: FETAL SURVEILLANCE

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/Patricia Romanelli/
Patricia Romanelli

SECOND APPEAL BRIEF PURSUANT TO 37 CFR § 41.37 AND MPEP § 1204.01

Dear Sir:

This Appeal Brief is filed in furtherance of the Second Notice of Appeal, filed concurrently herewith.

By way of background, the Examiner issued a second rejection of the claims in this Application in an Office Action mailed January 25, 2010. Rather than reply to this Office Action, Applicants filed a Notice of Appeal on June 25, 2010 and an Appeal Brief on August 25, 2010. Instead of filing an Answer, the Examiner reopened prosecution, again rejecting the claims, on grounds similar to those of the prior rejection. Applicants, therefore, appeal again and submit this brief to meet the Examiner's third rejection of the claims.

I. REAL PARTY IN INTEREST

The real party in interest is Monica Healthcare Limited, assignee of the above-identified application and located at University Park, Nottingham, United Kingdom NG7 2RD.

II. RELATED APPEALS AND INTERFERENCES

This Appeal Brief is filed in response to the Examiner's Office Action mailed December 27, 2010. There are currently no other appeals or interferences that will directly affect, be affected by, or have a bearing on the Board's decision in this appeal. However, copending U.S. Patent Appln. No. 12/195,481 (the "'481 Application") claims the benefit of the instant application and contains related subject matter. The claims of the '481 Application are currently under rejection.

III. STATUS OF CLAIMS

Claims 1-39 currently stand as rejected and have been rejected three times. The rejection of Claims 1-39 is again being appealed.

IV. STATUS OF AMENDMENTS

Concurrent with Applicants' filing of the original Notice of Appeal on June 25, 2010 and in response to the Examiner's 35 U.S.C. § 112 indefiniteness rejection of Claims 1-39, Applicants had submitted amendments to Claims 1 and 22. Claim 1 was amended to clearly recite structure, while Claim 22 was amended to clearly recite method steps. The amendments were entered by the Examiner.

No amendments have been submitted subsequent to the Examiner reopening prosecution.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The claimed subject matter relates to apparatus (Claim 1) and a method (Claim 22) for detecting both the spatial and temporal behavior of a fetus. The apparatus includes an input (31, Figure 8) for receiving electrocardiogram (ECG) data from a set of electrodes (11-14, Figure 8) that are adapted to be attached to a maternal abdomen. See Specification at page 14, lines 5-7, 19, and 20. The apparatus also has a waveform pre-processor for identifying a succession of fetal ECG complex waveforms within the received data (40, Figure 8), page 14, lines 20-26, and a waveform processor (50, Figure 8) that determines the differences in the shapes of a succession of fetal ECG complex waveforms over time. See page 14, line 28 to page 15, line 5.

The waveform processor 50 has at least one of : (a) a comparator (51, Figure 8) that is used to match the ECG complex waveforms to one of a plurality of stored templates (specification, page 15, lines 17-25, 27-32); (b) a phase detector for detecting a change in the phase of one of the ECG complexes relative to an adjacent ECG complex (specification, page 13, lines 6-14 and page 16, lines 20-29); and (c) an integrator that detects changes in the amount of positive and/or negative energy during the period of time (specification, page 13, lines 15-20 and page 17, lines 1-10).

The apparatus has an event logger (70, Figure 8) that determines the number of fetal body movements during a period of time. See page 16, lines 3-9 and page 16, lines 29-32. Using the components described above, the claimed invention allows the user to accurately determine and record the spatial and temporal behavior of a fetus. See page 1, lines 3-4.

The claimed method for monitoring the fetus's behavior comprises the step of obtaining the fetal ECG data over a period of time. See page 14, lines 10-22 and page 15, lines 19-22. A succession of fetal ECG complex waveforms is identified within the data, page 14, lines 23-26, and the differences in the shapes of the succession of fetal ECG complex waveforms are

determined over time. See page 14, line 32 to page 15, line 5. More specifically, the differences are determined by one or more of the steps of (1) matching the ECG complex waveforms to a plurality of stored templates, page 15, line 17 to page 16, line 20, (2) detecting a change of phase of one ECG complex relative to an adjacent ECG complex, page 16, lines 20-29, and (3) detecting changes in the amount of positive and/or negative energy in the fetal ECG complex waveforms by integration (page 17, lines 1-10).

Finally, the method for monitoring the fetus's behavior includes the step of determining a number of fetal body movements during the period of time from the differences. See page 13, lines 15-20 and page 17, lines 1-10.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection presented for review are (1) whether Claims 1-39 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent Publication No. 2001/0014776 to Oriol et al. (Oriol '776) in view of U.S. Patent No. 4,211,237 to Nagel (Nagel), U.S. Patent No. 5,088,498 to Beach et al. (Beach), and U.S. Patent No. 5,596,993 to Oriol et al. (Oriol '993).

VII. ARGUMENT

A. Rejection of Claims 1-39 under 35 U.S.C. §103(a) over Oriol ‘776 in view of Nagel, Beach, and Oriol ‘993.

Claims 1-6, 8, 10-14, 18-26, 29-33, and 37-39

Waveforms Versus Heart Rate Plot

With regard to Claims 1 and 22, the Examiner asserts that Oriol ‘776 teaches a waveform processor for determining the differences in the shapes of a succession of fetal ECG complexes over time. The Examiner also asserts that Oriol ‘776 teaches using a comparator and an event logger that determines the number of fetal body movements in a given period of time. See page 3, lines 16-22 of the USPTO Office Action dated December 27, 2010 (the “Office Action”). Applicants respectfully disagree with the Examiner’s characterization of the disclosure and maintain that the Examiner reads too much into Oriol ‘776.

An electrocardiogram (ECG) is a diagnostic tool that measures and records the signal strength of the voltage produced by the heart during a heartbeat. The voltage is measured through electrodes that are placed on the patient’s body and the signal strength is plotted versus time. As used in Applicants’ specification, an “ECG complex waveform” refers to the shape and form of the voltage signal (that is, the amplitude versus time) that is received by the ECG apparatus and is plotted in two dimensions. See Figure 4 of the drawings for a typical adult ECG waveform.

Applicants’ invention relates to determining the position or presentation of a fetus based on the shape of the ECG waveform. The fetus’s presentation can be determined analyzing the shape of the waveform in conjunction with the configuration of the electrodes on the patient’s body. Specifically, the processor analyzes the fetal ECG data to locate specific features, such as a QRS complex. See page 14, line 29 to page 15, line 5 of the Applicants’ specification.

Once these features have been identified in the fetal ECG data, the processor may find the temporal and spatial variations between individual fetal ECG waveforms. Stated differently, the processor analyzes the shape of each fetal ECG waveform to determine whether there are any differences between them. See page 10, lines 21-22 and page 14, line 28 to page 15, line 5 of Applicants' specification. If the processor determines that the difference between waveforms exceeds a predetermined threshold, the processor determines that a fetal movement "event" has occurred. See page 14, line 32 to page 15, line 5 of Applicants' specification.

The Examiner asserts that that the processor of Oriol '776 determines the differences in the shapes of a succession of fetal ECG complex waveforms because the expert subsystem (element 16) is involved in the "fetal assessment process." See page 3, lines 16-19 of the Office Action. A careful review of Oriol '776 shows, however, that the function and components of the expert system do *not* analyze the fetal ECG waveform (the signal strength plot) but, instead, looks at the *heart rate* of the fetus.

The expert subsystem is described in paragraphs [0103]-[0112] of Oriol '776. Specifically, Oriol '776 describes in paragraphs [0104]-[0107] that the expert subsystem is a "hybrid" system that contains rule-based modules and neural networks that break down the analysis of the fetal heart rate into specific tasks, i.e. assigning a behavioral state to the fetus, classification to the deceleration pattern, classification of the acceleration pattern, and analysis of uterine activity. As described in paragraphs [0108], [0110], [0111], and [0112] of Oriol '776, proper determination of these variables depends on the *heart rate* (or *frequency* of the fetus's heart beats), but Oriol '776 does not analyze the plot of the *signal strength* (the shape) of the fetal ECG waveform. See Figures 1A, 2A, 3A, 4A, 5A, 6, and 7A of Oriol '776, which show plots of the fetal heart rate versus time. As such, Oriol '776 does not teach a waveform

processor that determines the differences in the shapes of the ECG waveforms, as the Examiner asserts.

Determining Differences Between Waveforms

Further, the Examiner argues that Oriol '776 teaches determining the differences in a succession of fetal ECG waveforms. In support of this assertion, the Examiner argues that Oriol '776 teaches analysis of the shape of the plot of the fetal heart rate in order to determine whether the patient is having variable or lateral decelerations. See page 6, lines 7-12 of the Office Action.

As described in paragraph [0071] of Oriol '776, a deceleration is a decrease in the heart rate of the fetus that is coupled to the occurrence of a contraction. As shown in Figure 5A, the plot of the fetal heart rate may show increases or decreases over time due to the occurrence of a contraction. Paragraph [0071] teaches that decelerations can be either uniform or variable, where uniform decelerations have gradual onsets and offsets and variable decelerations do not. The type of deceleration is classified by the shape of the fetal heart rate plot. See paragraph [0071]. On this basis, the Examiner asserts that Oriol '776 teaches determining the differences between fetal ECG waveforms and, in doing so, the Examiner effectively equates the plot of the *heart rate* to the plot of the *signal strength* (electrocardiogram waveform), which is inaccurate.

Oriol '776 forms a plot of the heart rate by tracking the frequency of hundreds or even thousands of heartbeats over time. The “shape” of this plot, i.e. the decrease in the fetal heart rate, is then analyzed to determine whether the decelerations are uniform or variable. Neither the heart rate itself, nor the plot of the heart rate, discloses anything about the position or presentation of the fetus. Instead, they only show whether the fetal heart beat is speeding up or slowing down and whether the decelerations in fetal heart rate are uniform or variable.

In contrast, Applicants analyze the entire shape of *each* fetal electrocardiogram (ECG) waveform to determine the fetus's position at that moment in time. However, Oriol '776 does not analyze the entire individual waveform, but collapses the waveform to a single event and analyzes many of these events in order to determine the heart rate and to classify the deceleration as uniform or variable.

The Examiner further argues that the heart rate trends, or plots, and their use in determining decelerations allow the user to determine fetal spatial presentation or position. See page 8, lines 15-18 of the Office Action. This assertion is simply not consistent with or supported by the disclosure of Oriol '776. Neither a decrease of the fetal heart rate, nor evidence of any deceleration (as shown by the shape of the fetal heart rate plot), correlates to an indication of fetal position within the uterus. Only the Applicants' analysis of the shape of the individual ECG waveforms, in conjunction with the particular arrangement of the electrodes, provides the indication of the fetus's presentation and position within the uterus.

Thus, it is clear that the claimed invention is very different from that of Oriol '776 in its method, the number, and purpose. That is, it analyzes the shape of the fetal ECG waveforms (instead of heart rate or plots of heart rate), it does so with *each* ECG waveform, and it does so to determine the *position* of the fetus in the uterus. As such, Oriol '776 does not teach an ECG waveform processor for determining the differences in the shapes of a succession of fetal ECG complex waveforms.

Trend Variables

Further with regard to Claims 1 and 22, the Examiner notes that she is interpreting the trend variables received over a period of time and represented on an ECG monitor as the technique-means used to match fetal ECG complex waveforms to a plurality of templates. See

page 4, lines 1-7 of the Office Action. The Examiner further asserts on page 7, lines 1-4 that the expert subsystem is what provides the configuration and output of the data that is used by a clinician. As such, the Examiner argues that “trend variables” of Oriol ‘776 (and represented by trend plots on an ECG monitor) are used by measuring or comparing them against a specific pattern. The Examiner cites paragraph [0131] of Oriol ‘776 in support of the pattern. Applicants again respectfully submit that this reads too much into the teachings of Oriol ‘776 for a variety of reasons.

First, Oriol ‘776 does not teach the use of any template whatsoever. A template, as described by the Applicants, is a predefined waveform pattern that is stored in a memory that is compared against the real-time waveforms received by the ECG monitor. Each template corresponds to a specific presentation and/or position. See Applicants’ specification page 15, lines 7-15 and Figure 5.

The Examiner cites to the “pattern” of paragraph [0131] of Oriol ‘776 in support of her assertion. According to paragraph [0131], the important variables of a trace, or plot, vary from one individual pattern to another. This “pattern” refers to a *heart rate* plot, or trace, that is associated with a *particular patient* (paragraph [0131], lines 11-13). Thus, the Examiner’s assertion is erroneous for two reasons: (1) the pattern again refers to a plot of the *heart rate*, not an electrocardiogram, and (2) it refers to the pattern of a particular patient, not a pre-stored blueprint, or archetype, against which real-time ECG waveforms are compared.

Similarly, the Examiner asserts on page 7, lines 5-10 of the Office Action that the “trend variables” of Oriol ‘776 are used by measuring or comparing the plots of the variables (such as a heart rate) against the specific pattern of paragraph [0131]. However, as described above, the “pattern” of Oriol ‘776 refers to the fetal heart rate trace for a particular individual, not a stored

template. Thus, any user comparing the trend plots against the “pattern” of paragraph [0131] would be comparing the patient’s data against itself. This, of course, is the opposite of the claimed invention because the Applicants compare the data against pre-stored templates.

Second, paragraph [0131] of Oriol ‘776 teaches that a *clinician* reviews the data, not the processor. As a result, Oriol ‘776 does not teach that the *processor* compares the *shape* of an ECG waveform against a *stored template* as is required by the claims.

Comparator

The Examiner further asserts that Oriol ‘776 teaches using a waveform processor with a comparator for matching the fetal ECG waveforms against templates. See page 3, lines 19-20 and page 7, line 18 to page 8, line 2 of the Office Action. Setting aside the fact that Oriol does not teach using templates or analyzing the ECG waveforms themselves, Oriol ‘776 does not teach the use of a comparator, either.

The Examiner does not provide explicit support in the Office Action for the assertion that Oriol ‘776 teaches a comparator and the Applicants can find no support in the specification of Oriol ‘776 for a comparator that matches the waveforms to a plurality of stored templates. As such, Oriol ‘776 does not teach the comparator of Claim 1.

Phase Detector

Finally with regard to Claims 1 and 22, the Examiner cites Beach in support for the assertion that it is known in the art to use a phase detector to determine a change in phase of ultrasound waves reflected at different depths. See page 4, lines 20-22 of the Office Action. The Examiner further asserts that it would have been obvious to one of skill in the art that the ultrasound technology of Beach could have been combined with the ECG technology of Oriol

‘776 and Nagel to provide the apparatus and method for detecting phase changes between waveforms. See page 9, line 19 to page 10, line 2 of the Office Action.

The combination of an ultrasound phase detector with an ECG apparatus is inappropriate because the two technologies are very different from one another. The ultrasound process is an active process that projects bursts of sound waves into the body and measures the reflections to generate a two dimensional image.

In contrast, ECGs involve passive monitoring of the natural electrical signals generated by the body or, in this case, the fetus and the mother. The ECG does not create an image but only creates a trace showing the signal strength versus time of the maternal and fetal hearts. Since the two technologies use very different signals, it would not have been obvious to one of skill in the art combine the ultrasound phase detection of Beach with the ECG apparatus of Oriol ‘776, Oriol ‘993, and Nagel.

Claims 7 and 27

Claims 7 and 27 are patentable at least for their dependence on Claims 1 and 22, respectively. As described above, the shape of the waveform, or signal strength versus time, in conjunction with knowledge of the electrode placement, gives the Applicants an indication of the spatial position of the fetus. See page 10, line 25 to page 11, line 6 of Applicants’ specification. However, none of Oriol ‘776, Nagel, Beach, or Oriol ‘993 teaches or suggests this critical concept presented by the Applicants. As such, Claim 7 and 27 are patentable in view of Oriol ‘776, Oriol ‘993, and Nagel for this additional reason.

Claims 9 and 28

Claims 9 and 28 are patentable at least for their dependence on Claims 1 and 22. Further, none of Oriol ‘776, Oriol ‘993, Beach, nor Nagel teaches an event logger that records occasions

on which the determined template changes. In paragraphs [0081] and [0094], Oriol '776 mentions briefly that a fetal movement analyzer can be used to detect the occurrence of movement but this falls well short of teaching the claimed step of recording the number of times that a recognized template changes.

The Applicants' recordation of the movements represents a substantial advance over the storage of ECG data in Nagel. Not only does the claimed system determine the position of the fetus from the shape of the fetal ECG waveform, it determines the *number* of changes in position by determining the number of times that the matching template changes. This capability is far beyond the teachings of cited references because the Applicants' apparatus records not only the *occurrence* of movement, but also the *frequency* and *type* of movement.

Claims 15 and 34

Claims 15 and 34 are patentable at least for their dependence on Claims 1 and 22, respectively. Further, the Examiner cites Oriol '993 for the proposition that it is known to use a time plot of the base line heart rate signal showing decelerations associated with the loss of variability (page 5, lines 1-3 of the Office action). On this basis, the Examiner asserts it would have been obvious to one of skill in the art to combine the phase detector of Beach with the time plot-representation of the baseline heart rate signal of Oriol '993 to determine the ECG of the fetus to provide an indication so that the physician can evaluate the heart rate and output data such as warnings and recommendations (page 5, lines 1-17 of the Office action).

As with Oriol '776, Oriol '993 is directed to analysis of the fetal *heart rate*, not individual *ECG waveforms*. As such, Oriol '993 also describes using the plots of the heart rate signal and the uterine contraction signal to analyze decelerations in the heart rate. See column 9,

lines 13-39. This is very different, however, from teaching the detection of changes in the relative proportions of energy *above* and *below* a baseline ECG reference.

As used by the Applicants, the changes in the positive and/or negative energy of the fetal ECG waveform can be used to determine when the shape of the waveform has changed, thereby indicating when the fetus has changed to a different spatial presentation or position. For example, this technique can be used to determine if the pattern has changed from type A to type B of Applicants' Figure 5.

While detection of the change can be done by a number of different methods, Applicants teach that the detection can be done by integration, or summing the area under the curve. Oriol '993 does not teach using the technique of integration. Instead, Oriol '993 looks at the plot only to determine a deceleration pattern of the fetal heart rate. The Applicants, however, use the information to look beyond the heartbeat, using the waveform to detect a change in presentation or position of the fetus itself. No combination of the cited references does this.

Claims 16 and 35

Claims 16 and 35 are patentable at least for their dependency on Claims 1 and 15 and Claims 22 and 34, respectively. Further, none of the references teaches or makes obvious using the isoelectric line as the baseline reference.

Claims 17 and 36

Claims 17 and 36 are patentable at least for their dependency on Claims 1 and 15 and Claims 22 and 34, respectively. Further, none of the references teaches or makes obvious the step of using the previous or average waveform as the reference.

Conclusion

In summary, the crucial distinction of the Applicants' invention over the prior art is that, unlike the prior art, it goes beyond simple plotting of the heart rate to determine the health of the fetus. The prior art provides only a limited view of the overall picture and does not look to the shapes of the waveforms themselves.

Conversely, the Applicants have determined how to extrapolate additional valuable data from the ECG signals to provide more of the overall picture by using the ECG signals to determine (through comparison with templates, phase detection, or integration) the *spatial position and presentation* of the fetus. Applicants also record the *number of changes* in position and/or presentation, providing a further indication of the well-being of the fetus. These features simply are not disclosed or made obvious by the prior art.

Applicants have demonstrated that the Examiner did not have substantial evidence to support her rejections in view of the prior art. Applicants, therefore, respectfully request the Board to reverse the Examiner's rejections and to order that a Notice of Allowance be issued on this patent application.

VIII. CLAIMS APPENDIX

1. Apparatus for monitoring fetal behaviour comprising:
 - (i) an input for receiving ECG data from a set of electrodes adapted to be attached to a maternal abdomen;
 - (ii) a waveform pre-processor for identifying a succession of fetal ECG complex waveforms within the received data;
 - (iii) a waveform processor for determining differences in the shapes of a succession of fetal ECG complex waveforms over time, the waveform processor including at least one of a comparator for matching the ECG complex waveforms to a plurality of stored templates, a phase detector for detecting a change of phase of one ECG complex relative to an adjacent ECG complex, and an integrator for detecting changes in the amount of positive and/or negative energy in the fetal ECG Complex waveforms; and
 - (iv) an event logger determining from the determined differences a number of fetal body movements during the period of time.
2. The apparatus of claim 1 further including a plurality of electrodes for positioning at different locations on the maternal abdomen.
3. The apparatus of claim 2 in which the number of electrodes is two.
4. The apparatus of claim 1 in which the waveform pre-processor includes a discriminator for discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform.

5. The apparatus of claim 4 in which the waveform pre-processor includes means for subtracting the maternal ECG complexes from the received waveform.
6. The apparatus of claim 1 in which the waveform pre-processor comprises means for identifying a QRS complex in the fetal ECG data.
7. The apparatus of claim 1 in which the waveform processor comprises:
 - (i) a memory storing a plurality of fetal ECG complex templates each corresponding to a specific fetal spatial presentation and/or position;
 - (ii) a comparator for comparing each of the identified fetal ECG waveforms with a set of predetermined ones of the fetal ECG complex templates and determining at least one template from said set of templates that best matches each identified fetal ECG waveform.
8. The apparatus of claim 7 in which the memory stores a plurality of fetal ECG complex templates each corresponding to a specific fetal spatial presentation and/or position relative to a specific one of a plurality of different electrode configurations.
9. The apparatus of claim 7 in which the event logger records occasions on which the determined template changes.
10. The apparatus of claim 7 further including means for selecting the set of predetermined fetal ECG templates according to a preselected one of a plurality of configurations of ECG electrodes positioned on the maternal abdomen.

11. The apparatus of claim 7 in which the set of predetermined fetal ECG templates includes templates corresponding to at least cephalic presentation, breech presentation, shoulder dorsoanterior presentation and shoulder dorsoposterior presentation.
12. The apparatus of claim 1 in which the waveform processor comprises means for detecting phase changes between successive fetal ECG complex waveforms.
13. The apparatus of claim 12 in which the waveform processor comprises means for detecting phase changes of one or more predetermined magnitudes between successive fetal ECG complex waveforms.
14. The apparatus of claim 12 in which the event logger records occasions on which a phase change occurs.
15. The apparatus of claim 1 in which the waveform processor is adapted to determine differences in fetal complex waveforms by detecting change in the relative proportions of energy of a fetal ECG complex waveform above and below a baseline reference.
16. The apparatus of claim 15 in which the baseline reference is the isoelectric line of a fetal ECG complex.
17. The apparatus of claim 15 in which the reference is derived from a previous or average fetal ECG complex waveform.
18. The apparatus of claim 1 further including a display for displaying a count of the number of fetal body movements detected.

19. The apparatus of claim 1 wherein the waveform processor further includes a fetal heart rate monitor.
20. The apparatus of claim 1 further including an alarm for indicating if the number of fetal body movements-during a period of time falls below a predetermined threshold.
21. The apparatus of claim 1 further including a memory for storing fetal body movement event data and an electronic interface for downloading said event data to a remote device.
22. A method for monitoring fetal behaviour comprising:
 - (i) obtaining fetal ECG data over a period of time;
 - (ii) identifying a succession of fetal ECG complex waveforms within the data;
 - (iii) determining differences in the shapes of a succession of fetal ECG complex waveforms over time, said step of determining differences including at least one of the steps of matching the ECG complex waveforms to a plurality of stored templates, detecting a change of phase of one ECG complex relative to an adjacent ECG complex, and detecting changes in the amount of positive and/or negative energy in the fetal ECG complex waveforms by integration; and
 - (iv) determining from the determined differences a number of fetal body movements during the period of time.
23. The method of claim 22 in which step (i) comprises obtaining fetal ECG data from a plurality of electrodes positioned at different locations on the maternal abdomen.
24. The method of claim 23 in which step (ii) includes the step of discriminating between maternal ECG complexes and fetal ECG complexes in a received waveform.

25. The method of claim 24 in which step (ii) includes subtracting the maternal ECG complexes from the received waveform.
26. The method of claim 22 in which step (ii) comprises identifying a QRS complex in the fetal ECG data.
27. The method of claim 22 in which step (iii) includes:
 - (i) comparing each of the identified fetal ECG waveforms with a set of predetermined fetal ECG complex templates; and
 - (ii) determining at least one template from said set of templates that best matches each identified fetal ECG waveform.
28. The method of claim 27 in which step (iv) comprises determining the number of successive occasions on which the determined template changes during the period of time.
29. The method of claim 27 in which the set of predetermined fetal ECG templates is selected according to a preselected one of a plurality of configurations of ECG electrodes positioned on the maternal abdomen.
30. The method of claim 27 in which the set of predetermined fetal ECG templates includes templates corresponding to at least cephalic presentation, breech presentation, shoulder dorsoanterior presentation and shoulder dorsoposterior presentation.
31. The method of claim 27 in which step (iii) comprises detecting phase changes between successive fetal ECG complex waveforms.

32. The method of claim 22 in which step (iii) comprises detecting phase changes of one or more predetermined magnitudes between successive fetal ECG complex waveforms.
33. The method of claim 31 in which step (iv) comprises determining the number of successive occasions on which a phase change occurs during the period of time.
34. The method of claim 22 in which the differences determined in step (iii) comprise change in the relative proportions of energy of a fetal ECG complex waveform above and below a baseline reference.
35. The method of claim 34 in which the baseline is the isoelectric line of a fetal ECG complex.
36. The method of claim 34 in which the reference is derived from a previous or average fetal ECG complex waveform.
37. The method of claim 22 further including the step of displaying or logging a cumulative count of the number of fetal body movements within the period of time.
38. The method of claim 22 further including the step of monitoring fetal heart rate.
39. The method of claim 22 further including the step of indicating an alarm condition if the number of fetal body movements during the period of time falls below a predetermined threshold.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.

The required fees as set forth in 37 C.F.R. §41.20(b)(1) and 37 C.F.R. §41.20(b)(2) have already been paid by charging Deposit Account No. 503982 of Momkus McCluskey, LLC. The owner of this Application is not claiming small entity status. Applicant believes that no fee is due, but the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to the same deposit account

Respectfully submitted,

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